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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/057,646 | 01/25/2002 | Harry R. Davis | CV01379K | 3480 |

24265 7590 11/12/2003

SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER

WANG, SHENGJUN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1617

DATE MAILED: 11/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/057,646 | DAVIS ET AL. | |
| | Examiner | Art Unit | |
| | Shengjun Wang | 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-81 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2-8</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 11-27,36-39,41,44-46,51,54,56,59,61,64,66,69,72,75,78 and 81.

Continuation of Disposition of Claims: Claims rejected are 1-10,28-35,40,42,43,47,48,50,52,53,55,57,58,60,62,63,65,67,68,70,71,73,74,76,77,79 and 80.

DETAILED ACTION

1. Claims 36-39, 41, 44-46, 49, 51, 54, 56, 59, 61, 64, 66, 69, 72, 75, 78 are 81 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

2. Applicant's election with traverse of invention group I, claims 1-35, 40, 42, 43, 47, 48, 50, 52, 53, 55, 57, 58, 60, 62, 63, 65, 67, 68, 70, 71, 73, 74, 76, 77, 79 and 80, and ezetimibe and nicotinic acid as elected species in Paper No. 10 is acknowledged. The traversal is on the ground(s) that if there is a linking claims encompassing the scope of pharmaceutical compositions and methods of treatment using the compositions, it is improper to restrict the invention. This is not found persuasive because inventions related to a product and a process of using the products, restriction is proper for reasons stated in the prior office action.

The requirement is still deemed proper and is therefore made FINAL.

Further Species Election

3. This application contains claims directed to the following patentably distinct species of the claimed invention: claims 7-27 recite various third active agents.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1-6, and 28-81 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

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thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Ann Marie Cannoni on November 4, 2003 a provisional election was made with traverse to prosecute the species recited in claim 10, simvastatin. Affirmation of this election must be made by applicant in replying to this Office action. Claims 11-27 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species.

The claims have been examined insofar as they read on elected invention and species.

Claim Rejections 35 U.S.C. 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-10, 28-35, 40, 42, 43, 47, 48, 50, 52, 53, 55, 57, 58, 60, 62, 63, 65, 67, 68, 70, 71, 73, 74, 76, 77, 79 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenblum et al. (US 5,846,966, IDS), in view of Kim (US 5,698,527, IDS) and Keller et al (WO 00/38725, IDS).

6. Rosenblum teaches the instant cholesterol absorption inhibitors and its application for lowering serum cholesterol. Rosenblum further teaches that the cholesterol absorption inhibitors may be employed in combination with other cholesterol lowering agents, such as simvastatin. See, particularly, the abstract, and the claims.

7. Rosenblum et al. do not teach expressly a combination of the cholesterol absorption inhibitor and nicotinic acid.

8. However, Kim teaches that nicotinic acid is a well-known cholesterol lowering agent, and is particularly useful in combination with cholesterol absorption inhibitors. See, particularly, the abstract, and column 32, lines 9-25. Keller et al. teaches various combinations of cholesterol lowering agents, including ezetimibe and nicotinic acid, for treating hypercholesterol associated disorders. See, particularly, the abstract, and pages 11-14.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to make a composition comprising ezetimibe and nicotinic acid, and optionally simvastatin.

A person of ordinary skill in the art would have been motivated to make a composition comprising ezetimibe and nicotinic acid, and optionally simvastatin because it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for

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same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus, the claimed invention which is a combination of two known cholesterol lowering sets forth prima facie obvious subject matter. See In re Kerkhoven, 205 USPQ 1069. Further, the prior art have suggested the usefulness of combination of different cholesterol lowering agents, particularly, cholesterol absorption inhibitor and nicotinic acid.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Patent Examiner

A handwritten signature in black ink, appearing to read 'Shengjun Wang', is written over a rectangular stamp. The stamp contains the text 'SHENGJUN WANG' and 'PATENT EXAMINER' in a bold, sans-serif font.

Shengjun Wang

November 6, 2003